



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/542,937

09/08/2006

Pedro Mata Lopez

U 015859-4

5381

140

7590

04/29/2008

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

KAPUSHOC, STEPHEN THOMAS

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,937	Applicant(s) MATA LOPEZ ET AL.	
	Examiner Stephen Kapushoc	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: Sequence Reports of 07/29/2005 and 01/11/2007.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-3, 5, 6, 9, 10, and 12, drawn to nucleic acid sequences, oligonucleotides, and kits comprising oligonucleotides.

Group 2, claim(s) 4, drawn to methods of oligonucleotide design and preparation.

Group 3, claim(s) 7, 8, 11, 13, 14, 15, and 16, drawn to methods of mutation detection comprising oligonucleotides.

Further Lack of Unity Restriction Requirement

2. If Applicants elect the invention of Group 1, Applicants shall further select: (i) a single specific combination of the particular mutations recited in claims 1, 2, and 3; (ii) a single particular combination of probes from the group consisting of SEQ ID NOs: 8, 11, 16, 17, 24, 29, 37, 147, and 154-259 (as recited in claim 6); and (iii) a single particular combination of probes from the group consisting of SEQ ID NOs: 2-7, 9, 10, 12-15, 18-23, 25-28, 30-35, 148-153 (as recited in claim 12). The particular SEQ ID NOs selected in (ii) and (iii) should be consonant with the mutations selected in (i). For claims reciting particular mutations or SEQ ID NOs, only claims requiring the selected mutations and SEQ ID NOs will be examined, and those claims will be examined only in so far as they require the selected particular mutations and SEQ ID NOs. Generic claims will be examined to their full generic extent.

If Applicants elect the invention of Group 2, Applicants shall further select a single specific combination of the particular mutations recited in claim 4. Claims pertaining to the subject matter of Group 2 reciting particular mutations will be examined only in so far as they require the selected particular mutations and SEQ ID NOs. Any generic claims that may be added, for example by amendment to the claims, will be examined to their full generic extent.

Art Unit: 1634

If Applicants elect the invention of Group 3, Applicants shall further select: (i) a single particular combination of probes from the group consisting of SEQ ID NOs: 8 11, 16, 17, 24, 29, 37, 147, and 154-259 (as required by claim 8) (i) a single particular combination of probes from the group consisting of SEQ ID NOs: 2-7, 9, 10, 12-15, 18-23, 25-28, 30-35, 148-151, and 153 (as recited in claim 11); (iii) a single specific combination of the particular mutations recited in claims 1, 2, and 3 (as required by claims 7 and 13-16; and (iv) a single particular combination of oligonucleotides from the group consisting of SEQ ID NO: 2-259 and specific oligonucleotides of the assay kits of claim 9, 10, or 12 (as recited in claim 16). Any particular SEQ ID NOs selected in (i) (ii) and (iv) should be consonant with the mutations selected in (iii). For claims reciting particular mutations or SEQ ID NOs, only claims requiring the selected mutations and SEQ ID NOs will be examined, and those claims will be examined only in so far as they require the selected particular mutations and SEQ ID NOs. Generic claims will be examined to their full generic extent.

Claim notes

3. Claims 4, 7, 8, and 11 are 'use' claims, which are thus not drawn to statutory patentable subject matter. Amendment of these claims to create statutory patentable subject matter may require further restriction of these claims.

Sequence Listing

4. It is noted that the Computer Readable From (CRF) of the Sequence Listing associated with this application was found to be defective, as such the application fails to comply with the Sequence Rules set forth in 37 CFR 1.821. See the attached Raw Sequence Listing Error Reports (reports from 07/29/2005 and 01/11/2007) included with this Requirement for Restriction. The subject matter of the pending claims requires a Sequence Listing.

In order for any response to this Office Action to be considered Responsive, the response must put the application in compliance with the sequence rules.

5. The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The common technical feature among the groups is a sequence corresponding to SEQ ID NO: 1. However, such a sequence is anticipated by the prior art. Fodor et al (US Patent Publication 2001/0053519). Fodor et al teaches a microarray that contains 10-mer polynucleotides spotted at discrete locations such that the total array represents every possible permutation of 10-mer oligonucleotide (e.g.: p.3, ¶33; p.10 ¶101; p.12 - Example 2). The array of Fodor et al comprises every 10-mer nucleic acid. Because of the comprehensive nature of the array of Fodor et al, the reference necessarily teaches probes with the required structural limitations of the claims.

Art Unit: 1634

Regarding the Further Lack of Unity Restriction Requirement, the different mutations encompassing different nucleotide content and probes, and combinations thereof, lack unity because they are structures that are different from each other. The different nucleotide content of the mutations and probes are composed of nucleotide sequences that are not common to one another.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

Art Unit: 1634

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent

Art Unit: 1634

Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Stephen Kapushoc/
Examiner, Art Unit 1634